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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/854,568	05/15/2001	Samuel Bogoch	9425/46702	8438

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EXAMINER

SAUNDERS, DAVID A

ART UNIT	PAPER NUMBER
1644	

DATE MAILED: 02/15/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/854,568	Applicant(s) BOGOCH, SAMUEL	
	Examiner David A Saunders, PhD	Art Unit 1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 October 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-13 is/are pending in the application.
- 4a) Of the above claim(s) 6-13 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

THE RESTRICTION

The claims pending are 1-13.

Applicant's election without traverse of Group I (claims 1-5) in the reply filed on 10/15/04 is acknowledged.

THE FILING DATE

The examiner is utterly confused about the lineage of this application because of the following discrepancies.

1) The Bibliographic data sheet shows this application as a CON of 08/031,562, which is a CIP of 07/744,649.

2) The preliminary amendment filed on 5/15/01 inserts a statement of the continuation status of this application with 08/031,562, after the title. After this insertion, there is a section head "cross-references to other applications" that lists the above noted 07/744,649 application plus numerous other applications in its ancestry.

3) The only declaration in this application claims benefit of no other application-- e.g. 07/744,649. It appears to be a copy of a declaration submitted in 08/031,562, of which the instant is a CON.

THE SPECIFICATION

The disclosure is objected to because of the following informalities: at page one, the lineage of applications recited under "cross-references..." is incomplete for the following reasons:

1) The current status of 07/744,649 is not given.

2) The office PALM system shows that 07/744,649 is a CON of 07/227,621; 06/281,883; and 06/019,078. The complete serial numbers, the filing dates, and the current status of each must be listed.

3) Applicant then lists numerous "continuation-in-part applications, without stating the relation of these to each other in the series -- i.e. each serial number must be followed by the recitation -- which is a CON of -- or -- which is a CIP of --.

4) For each of these listed "continuation -- in -- part" applications applicant must provide a complete serial number indicating what series each is in -- e.g. "05/", "06/" etc; also, applicant must indicate the filing date and the current status of each.

Finally, at page 17, recitation of "U.S. Pat. No. 4,976,957 (S.N. 07/744,649)" is improper because the '957 Pat. Issued from S.N. 07/281,883, not 07/744,649.

Appropriate correction is required.

The examiner is also notes that there are two copies of the specification in this case.

- 1) One of 19 pages filed on 5/15/01
- 2) One of 14 pages filed on 7/27/01

The examiner finds no statement with the filing of the latter that indicates no new matter was entered.

The substitute specification filed 7/27/01 has not been entered because it does not conform to 37 CFR 1.125(b) and (c) because: the statement as to a lack of new matter under 37 CFR 1.125 (b) is missing.

THE DRAWINGS

Upon review of the file of parent application 08/031,562, the examiner notes that fig. 1 is in color, of which there is only one copy; the corresponding fig. Instantly is not in color.

Color photographs and color drawings are acceptable only for examination purposes unless a petition filed under 37 CFR 1.84(a)(2) is granted permitting their use as acceptable drawings. In the event that applicant wishes to use the drawings in parent application 08/031,562 on file as acceptable drawings, a petition must be filed for acceptance of the color photographs or color drawings as acceptable drawings. Any such petition must be accompanied by the appropriate fee set forth in 37 CFR 1.17(h), three sets of color drawings or color photographs, as appropriate, and, unless already

present, an amendment to include the following language as the first paragraph of the brief description of the drawings section of the specification:

The patent or application file contains at least one drawing executed in color. Copies of this patent or patent application publication with color drawing(s) will be provided by the Office upon request and payment of the necessary fee.

Color photographs will be accepted if the conditions for accepting color drawings have been satisfied.

THE DECLARATION

The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

The oath or declaration is defective because: the declaration fails to claim benefit of any of the earlier filed applications, for which applicant claims benefit at page 1 of the specification.

The declaration is stale. The declaration appears to be a copy of that submitted in parent 08/031,562 on 5/11/93. This declaration states that the application was filed on 3/12/93, the signature is dated 4/14/91.

In response to the above objections to the specification and declaration applicant is required to

1) State in his remarks what he deems the filing date for which he is claiming benefit.

2) Delete the entire section on page 1, headed "cross references..." and insert a lineage consistent with his remarks.

3) Provide a properly executed declaration that claims benefit of prior applications consistent with his remarks.

Claims 1-5 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Each of claims 1 and 5 recites, in the preamble, "to produce and release antimalignin antibody." Thereafter the composition to be used is recited as a Markush group of "malignin, recognin M, recognin L, or a peptide..." This thus the examiner considers the claim as indicating that "malignin" is a genus having the species malignin, recognin M, and recognin L.

Pat, 4,976,957 of applicant, however, teaches that "Recognin" is a genus having the species astrocytin, Malignin, Recognin M and Recognin L; see cols. 1-3.

The genus – species relationship instantly is thus different from that in Pat '957. The examiner is confused. Has the terminology changed?

Claims 1-5 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The claims contain new matter.

The claim language "stimulating the immune system of a subject to produce and release antimalignin antibody" is new matter. Examiner cannot find this phrase anywhere in the specification, or in the original claims of parent 08/031,562. This language is in the instant abstract; however, the examiner cannot compare this language against that in the abstract of 08/031,562, because the examiner finds no abstract sheet in the file thereof. In the absence of the ability to compare, the examiner takes the recitation to be new.

The recitation introduces new matter because it literally encompasses not only the process of vaccination but, also, the immunization of a laboratory animal against malignin for the purpose of obtaining an anti-malignin antibody.

Claims 1-5 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The specification does not teach those of ordinary skill in the art show to use the claimed invention without undue experimentation.

First with respect to the claim language, the examiner notes that the phrase "stimulating the immune system of a subject to produce and release antimalignin antibody" in claims 1 and 5 does not literally recite the terms vaccine, or "prevent the development of clinical cancer", or "inhibit or destroy clinical cancer"---all terms in claims 1 and 2 that were before the BPAI during prosecution of parent 08/031,562. However, the examiner takes these terms as encompassing vaccination and preventing/treating

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cancer, because this is the only embodiment or utility disclosed. Applicant has not disclosed that this claim language pertains to immunizing a laboratory animal for the purpose of obtaining reagent antibodies against malignin. As stated by the BPAI, in their decision of 11/30/00, the claims must be enabled for their full scope, which includes vaccination.

Also, the malignin and recognin products recited in claims 1 and 5 were disclosed by applicant as present on any type of cancer cells, irrespective of its histological type (specification pages 2, 7, 19 for example). Thus the full scope of claim 1 involves immunizing (vaccinating) against any type of cancer with a vaccine, while claim 5 is drawn to a vaccine product. According to the art-accepted definition, a "vaccine" must protect the vaccinated patient from a specific disease.

"[V]accines...must by definition trigger an immunoprotective response in the host vaccinated; mere antigenic response is not enough." In re Wright, 999 F.2d at 1562, 27 USPQ2d at 1513. The specification does not define "vaccine" to have a meaning different from the art-accepted meaning. The claims thus are directed to a product and method that protects the vaccinated patient from developing clinical cancer, derived from any cell type, and that is effective in treating developed clinical cancer, derived from any cell type.

To enable the full scope of the instant claims, therefore, the specification must teach those of skill in the art how to prevent or treat clinical cancer, derived from any cell type, by administering anti-Recognin. The guidance provided must be such that a skilled artisan would reasonably conclude that the claimed agent would have the

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disclosed effect when administered to patients. See Fujikawa v. Wattanasin, 93 F.3d 1559, 1564, 39 USPQ2d 1895, 1899 (Fed. Cir. 1996) (“[T]est results need not absolutely prove that the compound is pharmacologically active....[However], there must be a sufficient correlation between the tests and an asserted pharmacological activity so as to convince those skilled in the art, to a reasonable probability, that the novel compound will exhibit the asserted pharmacological activity so as to convince those skilled in the art, to a reasonable probability, that the novel compound will exhibit the asserted pharmacological behavior.”).

“When rejecting a claim under the enablement requirement of section 112, the PTO bears an initial burden of setting forth a reasonable explanation as to why it believes that the scope of protection provided by that claim is not adequately enabled by the description of the invention provided in the specification.” In re Wright, 999 F.2d at 1562, 27 USPQ2d at 1513. Exemplary factors to be considered include “(1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims.” In re Wands, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988).

In this case, nearly all of the Wands factors weigh against enablement:

(1) The claims are extremely broad in scope, and read on the prevention or treatment of any type of cancer by administration of malignin, Recognin, or any other molecule that generates cross-reacting antibodies.

(2) No working examples or other detailed guidance are provided. The specification provides only a few prophetic examples with little or no experimental detail. See pages 17-19 of the specification.

(3) The prior art of record discloses no other antibodies to tumor antigens that successfully prevent or treat cancer.

(4) The basis of the invention's asserted activity is unsupported by scientific evidence. Even applicant has conceded that "[i]f inhibition of [cancer cell] proliferation is an immune process, as has been theorized, there is no direct evidence in human cancer for such an immune process, and the responsible mechanisms are unknown." Specification, pages 4-5. Thus, the nature of the invention is tentative and scientifically unsupported.

(5) Inventions involving physiological activity are highly unpredictable. See In re Fisher, 427 F.2d 833, 839, 166 USPQ 18, 24 (CCPA 1970) ("in cases involving unpredictable factors, such as most chemical reactions and physiological activity, the scope of enablement obviously varies inversely with the degree of unpredictability of the factors involved.").

On the other hand, the level of skill in the art of cancer treatment is very high. However, on balance, the Wands factors compel a conclusion that the guidance provided by the specification would not have enabled a person of skill in the art to practice the full scope of the claimed invention-i.e., to use anti-Recognin antibodies to prevent or treat any type of cancer-without undue experimentation. The burden is

therefore shifted to applicant "to provide suitable proofs indicating that the specification is indeed enabling." In re Wright, 999 F.2d at 1562, 27 USPQ2d at 1513.

As evidence that the claimed product and method would have been considered likely to be effective in preventing and treating cancer, applicant shows the cytotoxic and growth inhibiting effects of anti-Recognin seen in vitro. See specification, page 12. However, where in vitro testing is relied upon to establish a pharmacological effect, there must be a known correlation between in vitro test results and in vivo activity. See Fujikawa, 93 F.3d at 1565, 39 USPQ2d at 1900 ("[I]n in vitro results, in combination with a known correlation between such in vitro results and in vivo activity, may be sufficient to establish practical utility."). See also Cross v. Iizuka, 753 F.2d 1040, 1061, 224 USPQ 739, 748 (Fed. Cir. 1985) (practical utility shown where application disclosed in vitro activity and prior art disclosed similar in vitro and in vivo pharmacological activity of structurally similar compounds). Applicant has provided no evidence to show that there is a known correlation between the reported in vitro results and in vivo activity, nor are we aware of such a correlation for tumor antigen antibodies. Therefore, the disclosed in vitro results do not establish the utility of the claimed invention.

The examiner further notes that in vitro data showing cell killing or inhibition of cell growth in the presence of antibody is easy to obtain. Such a demonstration tells one of skill nothing about what is going on in vivo -- e.g. does humoral antibody penetrate tissue barriers in order to get to the cancer cells? Note also that what works in vitro could be thwarted in vivo, due to the presence of "blocking" factors (e.g. Stevenson, page 2254, col.2), the phenomenon of antigenic modulation (Stevenson,

page 2254, col.2) and other factors noted by Stevenson at page 2254 as providing for tumor "escape" from immunity.

The other evidence relied on by applicant also fails to persuade that the claimed vaccine and method would have been considered likely to be effective in preventing or treating all types of cancer. Applicant points to data showing that levels of anti-Recognin antibody are highest in patients who are diagnosed with cancer, and that the anti-Recognin level decreases on successful treatment of cancer (specification pages 14-15). Applicant also points to actuarial data which show a correlation between the level of patients' anti-Recognin antibody and the length of their survival after cancer diagnosis (specification pages 16-17).

Although the second correlation (higher anti-Recognin, longer survival) seems contrary to the first correlation (lower anti-Recognin, successful cancer treatment), the examiner accepts these as accurate. Nevertheless, it is a basic scientific principle that correlation does not mean causation. That is, the fact that a higher level of anti-Recognin is associated with longer survival of cancer patients would not lead a skilled artisan to conclude that anti-Recognin causes longer survival. Therefore, a person of ordinary skill in the art would not expect that artificially increasing the level of anti-Recognin would have the effect of increasing a patient's survival time.

Additionally, the examiner notes that applicant's disclosure offers little in the way of teaching that was not known in the prior art. For example the relationship of anti-malignin antibody level to the survival of cancer patients was analyzed by an actuarial method by Bogoch et al, Prognosis..., 31, 739-747, 1984. The in vitro cytotoxic effect of

anti-malignin antibody was known (Ibid, p. 746). In this reference applicant has hedged on the issue of whether active immunotherapy "will be clinically effective against cancer" this statement is consistent with the above stated position, that what was shown by the actuarial data was merely a correlation, rather than a teaching of a causal link that would lead one to conclude that anti-malignin/recognin antibody causes tumor regression.

Finally, the examiner is at a loss to determine just what it is that applicant has presently disclosed regarding the prevention or treatment of cancer by immunization with malignin/recognin that was not known at the time of Bogoch et al. (Protides). Applicant's disclosure has given no more than a prophetic immunization schedule of 1mg of antigen at days 0, 10 and 20 (page 17-18). These particular figures appear to be within the general range of time intervals used to produce high-titre antibodies in mammals. Applicant has stated that natural anti-recognin in humans is IgM (page 5); however, it appears to the examiner that the boosting injections contemplated at pages 17-18 would drive the immune response toward IgG production. Thus the examiner fails to see how the proposed immunization schedule would mimic what the subject's immune system would do naturally.

Apart from the stated dosage and days of vaccination, applicant has disclosed nothing that might advance the art of vaccination against tumors. There is no teaching of what adjuvant should be used; Bystryn (page 84, col.2) notes the need to further evaluate adjuvants in order to potentiate the immunogenicity of tumor antigens. Applicant provides no teachings of what immunomodulators/biological response

modifiers should be used with the vaccine. See Bystryn (page 84, col.2) and Stevenson (FASEB J., page 2256, col.1). Applicant has provided no direction as to how one should particularly conduct the immunization to incur the production of antibodies of a particular isotype (class/subclass) that may be effective in vivo; see Stevenson at page 2254, col.1; applicant has provided no information as to how to conduct the immunization so as to avoid undesirable effects, such as the development of tumor enhancing immune responses and the production of suppressor cells (Bystryn, page 85, col.1).

In summary applicant wants to usurp possession of the "Holy Grail" (Stevenson page 2250, col.1) of providing a tumor vaccine. In return applicant has offered nothing in particular to the public, except to name an antigen (malignin/recognin) which is present on all tumor types. The mere recognition of such an antigen however does not lessen the problems noted by Bystryn and Stevensen with respect to providing a particular protocol of immunization which will provide for a clinically effective response, instead of an ineffective enhancing response in vivo. Applicant is leaving it for others to conduct undue experimentation to determine what is the appropriate immunization protocol. In a quid pro quo patent system applicant has offered the public no new information that merits the reward of an exclusive right.

The above statement of the rejection has incorporated numerous excerpts of the text provided by the BPAI in their decision of 11/30/00. Though the claim language does not now recite "vaccine" the examiner has noted supra that a "vaccine" would be encompassed by the product of claim 5 and a "vaccination" would be encompassed by

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the process of claim 1, under the doctrine of res judicata the instant claims therefore remain rejected as nonenabled under 35 USC 112, first paragraph.

Before examination over the prior art, the effective filing date of the instant claims must be established.

The effective filing date is taken to be 3/15/93, which is the effective filing date of parent application 08/031,562. The examiner finds no teaching, in a literal sense of "stimulating the immune system of a subject to produce and release antimalignin antibody." While earlier applications may refer to the immunization of animals with malignin/recognin, for the purpose of producing antibodies to be harvested and used as immunochemical reagents, the examiner finds no teachings of the use of malignin/recognin for the prevention or treatment of cancer within the subject to which the malignin is administered. Clearly the instantly recited language encompasses this latter embodiment, given applicant's disclosure at specification pages 2 and 17 referring to a "vaccine."

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-5 are rejected under 35 U.S.C. 102(b) as being anticipated by Bogoch (4,976,957).

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Bogoch teaches preparations of malignin, Recognin-M or Recognin-L for the immunization of animals, in order to produce antibodies thereto. See col.4, lines 27+ and col. 24, lines 1+. The antibodies produced, as a result of such immunization are obtained from the blood serum of the animal. See col.24, lines 15, 29, 35 and 39, for example.

The rejections of claim 1 is properly stated because the process of "stimulating the immune system of a subject to produce and release antimalignin antibody" is precisely what would occur when one immunizes an animal against malignin, as at col. 24 of the reference -- i.e. the B-cells of the immune system are stimulated such that they release anti-malignin antibody into the humoral body fluids. It is noted that applicant has provided no lexicography that defines what is intended by the terms "subject" "stimulating the immune system", "produce and release". The examiner has given the broadest reasonable scope to these terms in stating the rejection. Applicant's claims also state no result of the "stimulating" and the "release" of the antibody; the claims therefore encompass the result that the antibodies are simply secreted into a humoral fluid, which can then be harvested, as in the reference.

Applicant apparently intends claim 1 to cover a process of vaccination. Since such a process is not disclosed in the reference, the instant claim is clearly of broader scope than of any claim that might have been drafted for pat. '957. Therefore the instant claim cannot be supported by the '957 patent, and applicant cannot claim benefit of its effective filing date, in whatever his intended lineage of related applications may be.

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Regarding claim 5, like considerations apply to its preamble. Even if the preamble were amended to clearly limit the intended use to vaccination, this would not overcome the rejection. The recited antigens were known for use for immunization -- irrespective of whether the result thereof is intended to be merely the production of antibody reagents or the production of antibody that protects the host/subject. Applicant has disclosed no particulars related to compositions to be used in the intended vaccination that would distinguish these compositions from those used to immunize for the purpose of merely obtaining a reagent antibody. Thus the instant composition is no different from that of the reference. Intended use cannot overcome anticipation of the same prior art composition.

Regarding claim 2, note col. 24, lines 9-10.

For claim 3, note col. 24, line 13.

Claims 1-3 and 5 are rejected under 35 U.S.C. 102(b) as being anticipated by Bogoch (EP 0,015,078).

The EP publication is of the same patent family as the US patent cited supra. The EP disclosure is essentially the same as that noted supra for the US. See page 7, lines 23+ and page 48, lines 12+, for example. Claims are rejected with like rational.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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Claims 1 and 3-4 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bogoch (US '957 or EP '078) in view of Chase.

Each Bogoch reference has been cited supra as anticipating instant claim 1, by virtue of immunizing a laboratory rabbit with malignin or recognin, such that its immune system is "stimulated to produce and release" antibody against such antigens.

The art of immunization to produce antibodies has no clear theoretical foundation for arriving at any particular regimen for immunization. Chase shows a variety of immunization regimens for producing antibodies against soluble protein antigens in rabbits (Table I). The booster injections are therein given as frequently as each day, or as far apart as several weeks. Applicant's recitation of 10 days and 20 days for giving boosting (2nd and 3rd) injections is clearly within this ball park. Since the schedules set forth in Table I appear to be arbitrary, the arbitrarily set times of 10 and 20 days would have been obvious.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David A. Saunders, PhD whose telephone number is 571-272-0849. The examiner can normally be reached on Monday-Thursday from 8:00a.m to 5:30p.m. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan, can be reached on 571-272-0841. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Saunders/tgd

January 26, 2005

David A. Saunders
DAVID SAUNDERS
PRIMARY EXAMINER
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